

## **EXHIBIT 3**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING )  
PHARMACY, INC., PRODUCTS LIABILITY )  
LITIGATION )  
 ) MDL No.: 2419  
 ) Master Docket No.: 1:13-md-2419-FDS  
\_\_\_\_\_)  
THIS DOCUMENT RELATES TO: )  
 )  
 )  
\_\_\_\_\_) All actions.

**PROPOSED ESI PROTOCOL**

This protocol shall apply to all discovery of electronically stored information. It may be supplemented or amended by subsequent agreement of the Parties in light of further developments.

**I. DEFINITIONS**

A. “Electronically stored information” or “ESI,” as used herein, means and refers to computer generated information or data of any kind, stored in or on any storage media located on computers, file servers, disks, tape, or other real or virtualized devices or media. The examples of ESI set forth below are not an admission that a type of ESI exists, that a Party is obligated to preserve it, or that it should be produced in this litigation pursuant to a Party’s discovery requests. Non-limiting examples of ESI (which are provided without waiving the right of any Party to object to the production of a specific type of ESI in this case, including but not limited to objections for relevance, undue burden, and/or inaccessibility) include:

- Digital communications (e.g., voicemail, instant messaging);
- All server-based e-mail communications (e.g., Lotus Domino .NSF, Microsoft Exchange .EDB, .PST, .OST);

- All web-based e-mail communications (e.g., Gmail, Yahoo, Hotmail);
- Word processed documents (e.g., Word or WordPerfect files and drafts);
- Spreadsheets and tables (e.g., Excel or Lotus 123 worksheets);
- Accounting application data (e.g., QuickBooks, Money, Peachtree data);
- Image and facsimile files (e.g., .PDF, .TIFF, .JPG, .GIF images);
- Sound recordings (e.g., .WAV and .MP3 files);
- Video and animation (e.g., .AVI and .MOV files);
- Databases (e.g., Access, Oracle, SQL Server data, SAP);
- Contact and relationship management data (e.g., Outlook, ACT!);
- Calendar and diary application data (e.g., Outlook PST, blog entries);
- Notes, notepads, and reminders;
- Online access data (e.g., Temporary Internet Files, History, Cookies);
- Presentations (e.g., PowerPoint, Corel Presentations);
- Network access and server activity logs;
- Project management application data;
- Computer aided design/drawing files;
- Archival/compression files (e.g., .RAR, .ZIP, .7z);
- Backup files (e.g., Veritas, GHO); and
- Virtualized ESI or remote storage devices (e.g., cloud-based, internet-based), including application, infrastructure, and data.

**B.** “Incremental Costs” are the reasonable costs of transferring data to Production Media (e.g., CD-ROM, DVD, external hard drive, etc.) and the reasonable cost of the Production

Media itself. For costs charged by a vendor, the producing Party will request and provide a separate invoice detailing the Incremental Costs being taxed to the receiving Party.

**C.** “Native format” means and refers to the format of ESI in which it was generated and/or as used by the producing Party in the usual course of its business and in its regularly conducted activities.

**D.** “Metadata” means and refers to information about information or data about data, and includes without limitation (i) information embedded in or associated with a native file that is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage, and/or validity of the electronic file and/or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is created, modified, transmitted, deleted, or otherwise manipulated by a user of such system.

**E.** “Static Image” means or refers to a representation of ESI produced by converting a native file into a standard image format capable of being viewed and printed on standard computer systems.

**F.** “Documents” has the meaning contemplated in the Federal Rules of Civil Procedure and applicable case law and includes, but is not limited to, writings, drawings, graphs, charts, photographs, sound recordings, images, and other data, data records, or data compilations.

**G.** “Media” means an object or device, including but not limited to a disc, tape, drive, computer or other device, whether or not in the producing Party’s physical possession, on which data is or was stored.

**H.** “Parties” means or refers to the named Plaintiff and Defendant in the above-captioned matter, as well as any later added plaintiffs and defendants.

## **II. SCOPE**

**A. General.** The procedures and protocols set forth in this Agreement shall govern the production of ESI in this matter, unless the Parties agree in writing to change them or they are changed by the Court. Without limiting the generality of the foregoing, the Parties will confer in good faith regarding proposed changes to the Agreement in view of specific discovery requests made during the course of this litigation and/or in view of issues arising after a Party commences collection of ESI and other documents and information. In the absence of agreement between the Parties to change this Agreement, any Party may apply to the Court for relief. Nothing in this Agreement constitutes the waiver or estoppel of a Party's right to seek amendments to this Agreement for good cause, including changed circumstances not known to the Party at the time the Parties entered this Agreement. Nor does anything in this Agreement waive the right of any Party to object to the production of certain documents or ESI, including on the basis of relevance, undue burden, and/or inaccessibility.

**B. Disputes.** The Parties shall meet and confer in good faith on any issues regarding ESI that arise under this Agreement or otherwise, including any relating to custodians and data sources. In the event the Parties cannot reach an agreement on a disputed matter, the Parties shall submit the matter to the Court. For any disputes regarding the most effective way to retrieve requested material from a database, server, computer, service provider, or similar Electronic Storage Facility (ESF), before filing a motion, the Parties must include in their meet and confer discussions a representative knowledgeable about the relevant ESF. Both sides should be prepared to discuss specifically the relevance of the information sought, other sources of similar information, the burden of producing the information, and the parameters of the search.

### **III. SEARCH TERMS AND PROTOCOL FOR ELECTRONIC DOCUMENTS**

Contemporaneously with serving responses and objections to another Party's requests for production (the "Responding Party"), the Responding Party shall identify:

1. The types of programs or systems in which the Responding Party's potentially discoverable ESI is generally stored, including whether such format is anticipated to pose any technological challenges to implementing a search protocols.
2. The categories of ESI, if any, that are accessible. Examples of such categories could include electronically stored data that is already segregated such that an electronic search is not necessary or electronically stored data that is kept in such a manner that the use of search terms would not be effective or would not be the most efficient manner to locate and produce the relevant ESI. All other categories of potentially responsive ESI shall be searched through the use of search terms, following the process identified below.
3. The custodians whose documents the Responding Party intends to search for responsive ESI and a list of custodians that the Responding Party intends not to search. The Responding Party's list of proposed custodians will include each such custodian's job title. Each Party shall retain the right, upon reviewing documents actually produced in the litigation and conducting other investigation and discovery, to request that files from additional custodians be searched later in the litigation. The Parties agree to meet and confer in good faith concerning any such requests.
4. The sources of data that the producing Party intends to search for responsive ESI, along with a list of any known sources likely to contain potentially discoverable information that it does not intend to search.

Within seven days of serving their objections and responses to another Party's requests for production, the Parties will also provide any existing organizational charts relating to departments within their organizations in which any of the custodians referred to in paragraph (3) above, work.

Within fourteen days of serving their objections and responses to another Party's requests for production, the parties shall meet and confer regarding the previously exchanged lists and information referred to above and:

1. Proposed keyword search terms (including semantic synonyms, code words, acronyms, abbreviations, non-language alphanumeric associational references to relevant ESI, etc.) to be used when searching for ESI.
2. Proposed exclusion criteria (including, but not limited to date restrictions) related to ESI searches.

Any objections to a proposed custodian or a proposed search term shall be made prior to or during this conference. Furthermore, if a Party does not object to the inclusion of a search term proposed by another Party, and is aware of any semantic synonyms of that term, such synonyms shall be provided to all Parties prior to or during this conference. Notwithstanding the foregoing, if any producing Party believes that additional search terms would be necessary to identify its own responsive documents, that Party shall recommend such additional term(s) be added to the list.

Within twenty-one days of serving their objections and responses to another Party's requests for production, the Parties shall circulate lists of agreed and disputed custodians and sources, agreed and disputed search terms, and agreed and disputed exclusion criteria. Notwithstanding the foregoing, in the event that a producing Party subsequently determines in

good faith that an agreed term should not have been included, the Parties shall cooperate in good faith to resolve the matter. Any Party proposing such modifications to the agreed search terms must demonstrate good cause for such modification. In the absence of a mutually acceptable agreement to modify the agreed searched terms, the Responding Party may submit the dispute to the Court.

No later than this point shall each Party begin collecting documents, ESI, and information in the possession of each agreed custodian and/or additional locations such as shared drives, distribution lists, department files, etc. (the “Collected Documents”).

To the extent reasonably possible, the producing Party shall apply all agreed search terms to all Collected Documents, including all related metadata. All queries shall be run in a non-case sensitive manner, unless otherwise agreed by the Parties. Queries of family groups (e.g., email and attachments) will be run against all members of a family group, and if any is responsive, the entire family group shall be treated as responsive. The application of the agreed search terms to the agreed custodians shall be done on a rolling basis, and need not await the identification of all Collected Documents or all custodians. If the Collected Documents include non-searchable documents, the producing Party shall disclose this fact, and the Parties shall cooperate in good faith to determine the basis for review and potential production of such non-searchable documents. Each producing Party may, at its election, review ESI that contains any agreed-upon search terms for responsiveness and privilege prior to production to the receiving Party.

The producing Party shall also apply all disputed search terms to a reasonable sample of the Collected Documents, including all related metadata; provided, however, that the producing Party reserves the discretion not to run searches and provide data for those terms which it believes, in good faith, are obviously and unreasonably overbroad (the “Refused Terms”).



Nothing herein shall preclude an opposing Party from challenging another Party's assessment of reasonableness. The Parties agree to meet and confer regarding any disputes that arise concerning the reasonableness of the sampling, including disputes concerning the methodology used to determine the sample.

On a rolling basis thereafter, each Party shall disclose, for each source of sampled documents, the number of aggregate and unique "hits" for each of the disputed search terms. The Parties shall, within one (1) week of such disclosures, meet and confer to discuss the utility of adding any, or all, of the disputed search terms. The Parties shall continue to meet and confer in good faith regarding any search process issues that arise throughout this process, including any appropriate sampling of the documents with disputed search term "hits" to determine the utility of particular disputed search terms.

If, at the end of the process described above, disputed search terms remain, the Parties will submit those terms to the Magistrate Judge in the form of a joint discovery letter with a discussion of the relevance and/or burden associated with each such term.

Once the files of a custodian are searched for all agreed terms (including any formerly disputed terms which, by agreement of the Parties or order of the Court, are encompassed therein), the producing Party shall not be under any obligation, absent a Court order, to re-search that custodian's files for additional search terms. Any Party proposing such additional search terms will have to demonstrate good cause for re-searching a custodian's files.

The Parties will continue to meet and confer regarding any search process issues as necessary and appropriate throughout this process.

This ESI protocol does not address or resolve any objection to the scope of the Parties' respective discovery requests, and it does not prevent any Party from undertaking additional searches of its own ESI for its own purposes at any time.

#### **IV. FORMAT OF PRODUCTION**

**A. Document Image Format.** Unless otherwise agreed to in writing by a requesting Party, the producing Party shall have the option of (a) producing documents electronically in native file format, or (b) electronically as a single-page Group IV "TIFF" image that reflects how the source document would have appeared if printed out to a printer attached to a computer viewing the file, along with the associated files and fields of metadata set forth below. A Party electing to produce documents in TIFF format pursuant to V.A.(b) shall bear the costs of producing the TIFF files, with such costs non-reimbursable and non-taxable pursuant to 28 U.S.C. § 1920 or any other state or federal cost-recovery provision. For those documents that a Party can establish could not reasonably be produced as an initial matter in their native file format, the producing Party shall not be precluded from seeking recovery or taxation of costs for conversion to TIFF format of such documents, provided that nothing in this section or the remainder of this protocol precludes the requesting Party from opposing any applications for shifting of costs.

1. If ESI has hidden text (e.g., track changes, hidden columns, comments, notes, markups, etc.) associated with it, the Parties shall produce the ESI in a form showing such hidden text to the extent reasonably practicable. When processing ESI for review and for production, to the extent reasonably practicable, the producing Party will instruct its vendor to force off Auto Date and force on hidden columns or rows, hidden worksheets, speaker notes, track changes, and comments. If producing hidden text is not reasonably practicable, the parties shall meet and confer regarding possible alternatives.

2. Accompanying a TIFF production shall be a multipage text (.TXT) file containing searchable text from the native file, including, with regard to email, the email header text, and the metadata as discussed later in this document.

3. Load files of the Static Images shall be created and produced together with their associated Static Images to facilitate the use of the produced images by a document management or litigation support database system.

4. The Parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

**B. Native File Format.** Spreadsheets (e.g., Excel, Lotus), video/audio files (e.g., .wav, .mp3, .aiff, .wmv), and such other document types upon which the Parties may agree, will be produced in native format, except where such files are redacted in accordance with applicable law or Court order. If production in native format is necessary to decipher the meaning, context, or content of a document produced in the document image format agreed to pursuant to paragraph V.A., the producing Party will honor reasonable requests made in good faith for either the production of the original document for inspection and copying or production of the document in native format. All documents produced solely in native format should (i) have an assigned document level Bates number, (ii) be renamed according to the assigned Bates number, and (iii) have a “nativepath” populated along with the metadata load file pursuant to the guidelines outlined in paragraph V.J. To the extent that a producing Party is also producing TIFF images of certain ESI, native file productions shall also be accompanied by a TIFF placeholder with the Bates number and original filename endorsed (“burned”) onto the image, as

well as any confidentiality designation associated with that document. The Parties agree that compliance with these provisions shall not constitute spoliation.

**C. Production of Hard Copy Documents.** If a producing Party has or intends to convert any hard-copy documents or records to Static Images, the producing Party shall provide the Static Image files and corresponding load files to the requesting Party pursuant to Section V.A. and the protocols set forth herein, or as otherwise agreed to by the Parties. A producing Party shall identify responsive hard-copy documents in accordance with its duties and obligations under the Federal Rules of Civil Procedure. Unless otherwise agreed to by the Parties, the requesting Party shall pay the reasonable Incremental Costs, if any, of creating its copy of the Static Images and corresponding load files.

**D. Document Unitization.** For files produced as TIFF images, each page of a document shall be electronically saved as an image file. If a document consists of more than one page, the unitization of the document and any attachments and/or affixed notes shall be maintained as it existed in the original when creating the image files. The producing Party shall produce a unitization file (“load file”) for all produced documents in accordance with paragraph V.L.

**E. Duplicates.** The Parties shall use reasonable, good faith efforts to avoid the production of duplicate ESI. To the extent that exact duplicate documents (based on MD5 or SHA-1 hash values) reside within a Party’s ESI data set, each Party may produce only a single copy of a responsive document or record (“Single Production Copy”), but the Parties are not required to do so. Exact duplicate shall mean bit-for-bit identity of the document content. For exact duplicate documents, the producing Party will produce the metadata described in section V.J herein for the Single Production Copy, as well as any such metadata that differs for

the duplicate document(s). The producing Party shall populate a field of data that identifies each custodian who had a copy of the produced document in addition to a separate field of data identifying the custodian whose document is produced. The Parties shall provide periodic updates to their load files if the Dup\_Custodian field must be updated to account for newly processed data. No Party shall identify and eliminate duplicates by manual review or some method other than by use of the technical comparison using MD5 or SHA-1 hash values outlined above.

**F. Color.** At the producing Party's option, hard copy documents and documents reduced to TIFF may be produced in black and white in the first instance. Notwithstanding the foregoing, the producing Party will endeavor to produce in a color format any documents reduced to TIFF that contain color in instances where the Producing Party is aware that the color is necessary to the meaning, context, or content of the document. In addition, the producing Party will honor reasonable requests made in good faith for either the production of the original document for inspection and copying or production of a color image of the document (and, in the case of a hard copy document, a color hard copy) where the requesting Party determines the color is reasonably necessary to decipher the meaning, context, or content of the document. Color production when reasonably necessary or requested will be at the non-reimbursable and non-taxable cost of the producing Party, unless otherwise agreed to in writing by the requesting Party.

**G. Bates Numbering and Other Unique Identifiers.** For files produced in the document image format agreed to pursuant to paragraph V.A., each page of a produced document, at the sole option and non-reimbursable and non-taxable cost of the producing Party unless otherwise agreed to in writing by a requesting Party, shall have a legible, unique page

identifier (“Bates Number”) electronically “burned” onto the image in such a manner that information from the source document is not obliterated, concealed, or interfered with. There shall be no other legend or stamp placed on the document image unless a document qualifies for confidential treatment pursuant to the terms of a protective order entered by this Court in this litigation, or has been redacted in accordance with applicable law or Court order. In the case of confidential information or highly confidential information, as defined in a protective order, or materials redacted in accordance with applicable law or Court order, a designation may be “burned” onto the document’s image at a location that does not obliterate or obscure any information from the source document. Any Party producing ESI in a native format shall produce the document in the format agreed to pursuant to paragraph V.B.

**H.** Production Media. Documents shall be produced on CD-ROM, DVD, external hard drive (with standard PC compatible interface), or such other readily accessible computer or electronic media as the Parties may hereafter agree upon (the “Production Media”).

**I.** Electronic Text Files. Where documents maintained in the ordinary course of business contain searchable text, text files shall be produced reflecting the full text that has been electronically extracted from the documents (“Extracted Text”), including any hidden text. Where such documents are no longer searchable because they have been converted to Static Images by the producing Party, the producing Party shall provide OCR text files at its own expense. Where documents do not contain searchable text as they are maintained in the ordinary course of business, the requesting Party shall pay the reasonable Incremental Costs, if any, associated with obtaining its own copy of the OCR text files generated by the Producing Party, if any. With respect to emails, the Extracted Text shall include email header information, including to, from, cc, bcc, subject, date, and the names of attachment files. The Extracted Text

shall be labeled and produced on Production Media in accordance with the provisions of paragraph V.H above, “Production Media.” The text files shall be produced in multi-page text file format and will be named in such a way that they can be associated with their corresponding Static Images in databases utilized by commercially available document management or litigation support software.

**J. Metadata.** The Parties agree to produce the following metadata fields (to the extent available) to accompany each produced ESI file. Unless otherwise specified, by producing metadata, the producing Party affirms that such metadata came from its records, with the exception of vendor-entered source/custodian and document/production number fields.

- BegDoc (beginning Bates number of the first page of a document)
- EndDoc (ending Bates number of the last page of the document)
- BegAttach (Bates number associated with the first page of a parent document)
- EndAttach (Bates number associated with the last page of the last attachment to a parent document)
- Attach Count (number of attachments to an email or e-doc)
- DocTitle (e-docs only)
- ThreadID (emails only)
- Thread\_in\_Reply\_to (emails only)
- Thread\_references (emails only)
- File/folder path (the full path to the file at its original location)
- ParentID (beginning Bates number for the parent email or e-doc)
- Attchids (beginning Bates number(s) for the attachment(s) associated with a parent e-mail or e-doc)
- FamilyID (An ID that is unique to the entire family group (email and attachments))
- Family Date (for emails and attachments only, corresponding to the sent or received date of the email to which the attachment is linked)
- MessageID (emails only)
- Sent Date (for emails and calendar invitations)

- Sent Time (for emails and calendar invitations)
- Last Modified Date (all documents)
- Last Modified Time (all documents)
- Created Date (all documents)
- Created Time (all documents)
- Received Date (for emails only)
- Received Time (for emails only)
- Call Start (start date and time of a calendar or appointment)
- Last Accessed Date (all documents)
- Last Accessed Time (all documents)
- Last Print Date (for e-docs)
- Author (e-docs only)
- From (“From” field in emails)
- Recipients (“To” field in emails)
- cc: (for emails only)
- bcc: (for emails only)
- Subject (“Subject” field in emails)
- Participants (names included in a meeting invitation)
- Attach Title (email attachments title list)
- Application (type of application used to generate the document)
- Custodian
- Duplicate custodian (the name of any custodian whose duplicate file was removed during production)
- MD-5 Hash Value
- SHA-1 Hash Value
- Page Count (number of pages in a document)
- Original File Name (the original file name of an e-doc or attachment to an email)
- Doc extension (the file extension of a document)
- Full Text (the full path to the OCR/extracted text file on Production Media)
- NativeLink (the full path to the native file produced)



Notwithstanding the foregoing, the Parties will meet and confer in good faith prior to the production of documents, with technical experts as needed, to clarify or resolve any issues (e.g., definitions of metadata fields, inconsistencies, burden) concerning the production of metadata.

**K.** Attachments. Email attachments and embedded files or links must be mapped to their parent by the Document or Production number. If attachments and embedded files are combined with their parent documents, then “BeginAttach” and “EndAttach” fields (or the functional equivalent, depending on the production format chosen) listing the unique beginning and end number for each attachment or embedded document must be included, when possible.

**L.** Load Files. The Parties agree to produce the following load files to accompany each production volume:

OCR and Extracted Text Files (.TXT Files):

- Single text file per document containing all the document's pages
- Pages separated by form feed character (decimal 12, hex 0xC)
- Filenames should be of the form:

<Bates num>.txt

Where <Bates num> is the BATES number of the first page in the document.

- Text must be encoded in UTF-8.

Image Files:

- Single page per image
- TIFF is Group IV compression, 300 dpi unless color or grayscale image is necessary, then .JPG would be acceptable
- Filenames should be of the form:  
“<Bates num>.<ext>,” where <Bates num> is the BATES number of the page, and <ext> is the appropriate extension for the image format (.jpg, .tif).

Index Files:

- “Concordance Default” delimited text file utilizing the following characters:
  - The “comma” delimiter is “¶” (020)
  - The “quote” delimiter is “p” (254)

- The “new line” delimiter is “@” (174)
- First line must contain the column/field names (set forth in Paragraph 1(c) herein)
- Every row must have the same number of columns/fields (empty values are acceptable)
- All records must contain the quote “p” character and the comma “¶” character for every entry.
- DATE Fields (cannot contain zeros such as, 00/00/0000 or 11/00/2012 value)
- Text must be encoded in UTF-8

**M.** Structured data. To the extent a response to discovery requires production of discoverable ESI contained in a database, in lieu of producing the database, the Parties agree to meet and confer, with an understanding of which fields are relevant, regarding queries to be made for discoverable information or upon the sets of data or fields to be included and generate a report in a reasonably usable and exportable electronic file (e.g., Excel or CSV format) for review by the requesting Party or counsel. Upon review of the report(s), the requesting Party may make reasonable requests for additional information to explain the database schema, codes, abbreviations, and different report formats or to request specific data from identified fields.

## **V. OBJECTIONS TO ESI PRODUCTION**

**A.** Documents that present imaging or form production problems (including encrypted and/or protected files identified during the process of ESI) shall be promptly identified and disclosed to the requesting Party; the Parties shall then meet and confer to attempt to resolve the problems.

**B.** If either Party objects to producing the requested ESI on the grounds that such information is not reasonably accessible because of undue burden or cost, or because production in the requested format is asserted to be not reasonably accessible because of undue burden or cost, the Party, at or before the time the production is due under the Federal Rules of Civil

Procedure, agreement of the Parties, or order of the Court, shall describe the nature of the objection with reasonable particularity and indicate whether the producing Party is willing to offer an alternative. The Parties will promptly meet and confer in an attempt to resolve the objections if necessary.

**C.** If a producing Party learns that responsive ESI that once existed was lost, destroyed, or is no longer retrievable as a result of acts or circumstances not occurring in the ordinary course of business or not occurring in accordance with the Party's document retention policies, the producing Party shall comply with its obligations under the Federal Rules of Civil Procedure to explain where and when the responsive ESI was last retrievable in its original format and to disclose the circumstances surrounding the change in status of that responsive ESI, whether that information is available from other sources, and whether any backup or copy of such original responsive ESI exists. Nothing in this paragraph is intended to expand or limit the obligations under the Federal Rules of Civil Procedure.

## **VI. Miscellaneous**

**A.** Cooperation. The Parties shall, as necessary, meet and confer to exchange information regarding issues associated with any electronic production of ESI, including, but not limited to, database field definitions and structure or document delivery mechanisms.

**B.** Variance. Any practice or procedure set forth herein may be varied by agreement of the Parties without order of the Court. Failure of the Parties to agree on any modifications may be raised with the Court as necessary and in accordance with the Federal Rules of Civil Procedure and the Local Civil Rules.